UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION MDL No. 1456

THIS DOCUMENT RELATES TO:

ALL CLASS ACTIONS

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO THE TRACK 1 DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH RESPECT TO CLASS 3

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I. INTRODUCTION

Plaintiffs proceed on the theory that Defendants have committed unfair and deceptive acts or practices in violation of Mass. Gen. Law ch. 93A, § 2 (hereinafter "G.L. ch. 93A").

Based on the overwhelming weight of evidence detailed in this memorandum and in Plaintiffs' affirmative motion for summary judgment as to Class 1 and 2 there is no genuine issue of material fact that (i) AWP was the reimbursement benchmark for Class 3 payments, and each Track 1 Defendant consistently recognized that it was; (ii) Defendants AstraZeneca, BMS, Johnson & Johnson ("J&J"), and Schering-Plough controlled the AWPs that were published for the Part B drugs that are the subject of this litigation (the "Subject Drugs"); (iii) those AWPs did not reflect averages of real prices in the marketplace, did not include a multitude of discounts that, pursuant to Office of the Inspector General Guidelines (the "OIG Guidelines"), should have been included, and that (iv) each Track 1 Defendant secretly and covertly manipulated and marketed the spreads on their Subject Drugs in order to protect or gain market share. As a result of the fictitious and inflated AWPs either reported or republished by the Track 1 Defendants, the Class 3 Plaintiffs and Class members substantially overpaid for Subject Drugs.

This course of conduct is both unfair and deceptive under G.L. ch. 93A and other similar state statutes as a matter of law. It is unfair because the practice: (i) is within the penumbra of

¹ "AstraZeneca" is used to refer to AstraZeneca, PLC; Zeneca, Inc.; AstraZeneca Pharmaceuticals L.P.; and AstraZeneca U.S.

² "BMS" or the "BMS Group" is used to refer to Bristol-Myers Squibb Co.; Oncology Therapeutics Network Corp. ("OTN"); and Apothecon, Inc. Where appropriate, OTN is sometimes referred to separately.

³ "J&J" refers to Johnson & Johnson; Centocor, Inc.; Ortho Biotech, Inc. ("OBI"); McNeil-PPC, Inc.; and Janssen Pharmaceutica Products, L.P. Where appropriate, OBI is referenced separately.

⁴ The Schering-Plough Group consists of the parent-corporation, Schering-Plough Corporation ("SP"), and its wholly-owned subsidiary, Warrick Pharmaceuticals Corporation ("Warrick"). In this memorandum, "SPW" is generally used where the evidence applies against both parent and subsidiary. Where a distinction needs to be made, "SP" or "Warrick" are referenced separately.

common-law, statutory, or other established concepts of unfairness; (ii) is immoral, unethical, oppressive or unscrupulous; and (iii) causes substantial injury to consumers, competitors or other business people. The course of conduct is also deceptive in that it has an undeniable capacity to deceive. *See* Plaintiffs' Memorandum in Support of Motion for Partial Summary Judgment Against All Track 1 Defendants at Part IV.B.

Defendants now claim that summary judgment in their favor is appropriate against Class 3. Defendants claim that not one member of Class 3 was deceived largely because one Class member, BCBSMA, allegedly knew of and blessed the practices described in this litigation. In essence, Defendants claim they were thus free to create spreads with no limits and to engage in spread marketing practices with immunity despite their knowledge that their actions directly impacted third-party payors. This argument ignores a substantial body of evidence that members of Class 3, including BCBSMA, did not know: (i) the true extent of spreads on the Subject Drugs; (ii) that most of the Subject Drugs had a spread exceeding a reasonable relationship to acquisition costs; (iii) were unaware of Defendants' secret tactics to market the spread to doctors; and (iv) were unaware of the efforts by Defendants' own employees to keep these spread marketing efforts secret and to commit them only to "scratch paper." Why commit something to scratch paper if everyone knew and did not care? Ironically, yesterday Schering-Plough pled guilty and agreed to pay a total of \$435 million, in response to federal and state charges. Among the allegations are that Schering paid doctors \$500 per patient that were given Temodar and Intron-A. That \$500 lowered the cost to each doctor, rendering the AWP even more inflated. Where is the evidence the Class 3 members should have been aware of these payoffs?

Defendants' motion is almost entirely premised on a distorted presentation of evidence relating to BCBSMA, seeking to foreclose an entire class of payors based on such evidence of a

single Class member. However, summary judgment as to Class 3 is not appropriate where there is no evidence to support a claim that class representative Pipefitters Local 537 Trust Funds ("Pipefitters"), or other similarly situated Class members, knew of the AWP manipulation described above. And, as explained below, there is no evidence that BCBSMA itself knew of Defendants' practices. What BCBSMA did know was the existence of discounts to some physicians, and BCBSMA was aware of concerns raised in late 2004 by Congress about using AWP as a reliable benchmark. Such awareness did not inform BCBSMA that a fraud existed prior to 2004, or even to what extent it existed in 2004. Nor did such information reveal which Defendants were the wrongdoers or which drugs were subject to such manipulation.

Further, throughout the course of this litigation, Plaintiffs, in response to the "knowledge" defense, have challenged Defendants to demonstrate where they informed members of any Class of spreads they created for the Subject Drugs, or of the fact they were secretly promoting these spreads at the expense of Class members, or of the fact Schering was busy paying off doctors under the table. Defendants cannot do so. Nor can they show any knowledge of the specific marketing tactics employed by each Defendant and described in detail in Plaintiffs' affirmative motion for summary judgment as to Class 1.

Instead, Defendants show at best, that certain separate subsidiaries of third-party payors, for example, a subsidiary of BCBSMA that was a staff-model HMO and was closed in the late 1990s, purchased certain drugs at ASP. However, the parent organization at BCBSMA had no knowledge of such acquisition prices, utilized AWP for reimbursement purposes and was unaware of the AWP Scheme until 2003-2004. And, of course, Pipefitters and similar union funds are not alleged to have any such knowledge. In fact, Defendants have studiously avoided asking any witness if they were aware of the specific spreads at issue or of the specific marketing

practices of Defendants. Instead, their motion is supported only by innuendo and must fail.

Defendants also move for summary judgment on the grounds that their manipulation of AWP did not "cause" any harm. This argument is belied by Dr. Hartman's report and the Court's prior opinion, *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 207 (D. Mass. 2004), as well as by Judge Stearns' opinion in *Lupron*, where he found that the "argument borders on the frivolous." It is beyond dispute that if AWP was the reimbursement benchmark and proper AWPs were published Class members would have paid less for their drugs. It is also contradicted by Defendants' own admissions in their own documents that their conduct came at the expense of Class members – their words not ours.

As for the statute of limitations, Defendants' acts of concealment, which continued even after the lawsuit was filed, tolled the statute. Plaintiffs provide more than ample factual support to prove that the Class 3 claims fall within the "discovery rule" exception to the four year statute of limitations, and that Plaintiffs are entitled to rely on the fraudulent concealment doctrine given that Defendants actively hid the acquisition prices for their products prior to October 1997. Defendants cannot show that a single Plaintiff or member of Class 3 either knew or reasonably should have known of Defendants' fraud.

In sum, Defendants' motion is without merit.

II. PLAINTIFFS' COUNTER-STATEMENT OF MATERIAL FACTS

Rather than burden the Court with excess paper by repeating factual material already submitted to the Court in other briefing, Plaintiffs incorporate herein the separate Response of Class Plaintiffs to Statement of Undisputed Facts in Support of Track 1 Defendants' Motion for Summary Judgment filed with respect to Class 1 and 2; the Statement of Undisputed Material Facts set forth in Plaintiffs' Memorandum in Support of Partial Summary Judgment Against All

Track 1 Defendants (Part III of that brief) and Plaintiffs' supporting Rule 56.1 Statement; and the fact statements set forth in Plaintiffs' opposition briefing to the individual summary-judgment motions filed by each Track 1 Defendant. Plaintiffs further designate the Dec. 16, 2004 Rebuttal Declaration of Dr. Raymond Hartman in Support of Plaintiffs' Motion for Class Certification ("Dec. 16, 2004 Hartman Class Cert. Decl."); the April 7, 2006 Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment ("Hartman S.J. Opp."); the December 15, 2005, Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages ("Hartman Liab. Report") (Ex. 1); and the newly filed Declaration of Raymond S. Hartman in Response to Dr. Gaier's Declaration on Opposition to the Class 3 Summary Judgment Motion ("Hartman Class 3 Decl."); and Plaintiffs' Counterstatement of Undisputed Material Facts in Support of Their Opposition to the Motion for Summary Judgment as to Class 3, as setting forth material facts and opinions in opposition to this motion.

III. FACTUAL REBUTTAL

A. The Staff Model HMO

In the late 1990s, BCBSMA had a subsidiary called Medical West, Inc. ("Medical West"). Medical West was a staff-model HMO. That is, all of the physicians were employees and unlike BCBSMA main, these doctors purchased drugs. The main business units of BCBSMA do not purchase drugs but instead reimburse those who do. Certain BCBSMA insureds, a small percentage of BCBSMA's membership, received medical care through Medical West. Medical West did its own contracting and there was little contact between its employees

⁵ All references to "Ex." are to exhibits attached to the Declaration of Steve W. Berman in Support of Plaintiffs' Opposition to the Track 1 Defendants' Motion for Summary Judgment With Respect to Class 3 submitted herewith.

⁶ Declaration of Maureen Coneys in Support of Plaintiffs' Opposition to Track 1 Defendants' Motion for Summary Judgment With Respect to Class 3 ("Coneys Decl.").

and the divisions of BCBSMA who administered other health products. *Id.*, ¶¶ 12-13. Not only was there little contact, Medical West was a separate subsidiary that operated in a location different from all other BCBSMA personnel. *Id.*, ¶ 13. Information as to Medical West's drug reimbursement policy or acquisition costs was not shared with divisions of BCBSMA. *Id.*, ¶ 12. An analysis of the transaction data from drug purchases made by Medical West with the reimbursement price paid by BCBSMA, confirms the lack of shared information. Dr. Hartman analyzed BCBSMA claims data outside of the staff model HMO and found that "Average reimbursement rates are either very close to or greater than AWP, or they are within 15% of AWP." Hartman Class 3 Decl., ¶ 12, and Attachment B, which tracks for certain drugs the close relationship between AWP and BCBSMA's actual cost.

B. BCBSMA Reimbursements Are Tied To AWP

Throughout most of the Class Period, from 1995 to the present, it is undisputed that BCBSMA reimbursed based upon AWP even if its physician contracts do not expressly say so.⁷

In 1995, BCBSMA began using the AWP as a basis for reimbursement to physicians for physician-administered drugs. From 1995 to 1998, BCBSMA used 100% of AWP as the basis for establishing the reimbursement amounts in its fee schedules and related to physician reimbursement for physician-administered drugs. In 1998 and through the present, BCBSMA moved to using 95% of AWP as the basis for the reimbursement amounts set forth in these fee schedules. *Id.*, ¶ 8.

⁷ Declaration of Michael T. Mulrey in Support of Plaintiffs' Opposition to Track 1 Defendants' Motion for Summary Judgment With Respect to Class 3 ("Mulrey Decl."), ¶ 8. Mr. Mulrey, since 2000, is the manager of Professional Provider Reimbursement at BCBSMA.

The fee schedules maintained by BCBSMA, including the four fee schedules related to reimbursement for physician-administered drugs, are referenced in the contracts with physicians or physician groups.

Mr. Mulrey, in testimony elicited by and then ignored by Defendants, confirmed that AWP was the basis for reimbursement of physician-administered drugs at BCBSMA:

- Q. Okay. Currently today what is the amount in the fee schedules that is afforded to physicians for the administration of drugs to Blue Cross/Blue Shield of Massachusetts members?
- A. You are asking what the AWP was set at?
- Q. Is there a constant methodology utilized for all 22 drugs in each of the fee schedules?
- A. Right.
- Q. And is that methodology for the fee-for-service reimbursement based upon a percentage of AWP?
- A. Yes.
- Q. And what is that percentage?
- A. 95 percent.
- Q. How long has Blue Cross/Blue Shield of Massachusetts utilized a reimbursement amount of 95 percent of AWP to reimburse all drugs on all its fee schedules?
- A. Since '98 when Medicare made their change.

. . .

- A. 100 percent of AWP.
- Q. Starting in 1995, how did Blue Cross/Blue Shield of Massachusetts determine the AWP it used to calculate the amounts in its fee schedules?
- A. We basically just used Medicare's AWP.

- Q. When you say "Medicare's AWP," what are you referring to?
- A. Medicare's AWP fee schedule for their J codes.
- Q. Okay. So is it correct that Blue Cross/Blue Shield of Massachusetts did not calculate its own dollar amounts in the fee schedule but simply adopted the amounts that were specified in the Medicare fee schedules?
- A. Yes.⁸

All but a few capitated claims are paid based on these AWP based fee schedules, and those capitated claims are easily identifiable via BCBSMA's electronic database. Dr. Hartman's analysis of actual BCBS claims data supports the use by BCBSMA of the AWP reimbursement benchmark. *Id.*, ¶ 12.

C. BCBSMA Expected AWP To Be An Average

BCBSMA employees actually responsible for reimbursement expected AWP to be a meaningful number. Mr. Mulrey, the Manager of Provider Reimbursement, expected that "the AWPs that BCBSMA had been using as a basis for reimbursement was the price at which, on average, physicians were paying to purchase physician administered drugs." Mr. Mulrey's testimony was clear that, as an employee responsible for provider reimbursement, he understood AWP to be different than it really was:

- Q. I am asking what you understanding was. Okay? Let's just start with that point. In 2000, what was your understanding of the term AWP, or average wholesale price?
- A. It is the price that we would reimburse our providers, and it was the price at which we felt providers purchased their drugs at.

⁸ Ex. 2 (Mulrey Dep. at 60-63).

⁹ Mulrey Decl., ¶ 11.

¹⁰ Mulrey Decl., ¶ 14.

- Q. Okay. So it is your understanding it was your understanding in 2000 that it was the price at which providers purchased their drugs; is that correct?
- A. Yes.
- Q. So, in other words, it is your position that you understood that Blue Cross/Blue Shield of Massachusetts was reimbursing providers at their average cost?
- A. Yes. [pp. 87-88.]

. . .

- Q. So in 2003-2004, as a member of the provider reimbursement group, you learned that AWP was no longer, you know, from your perspective an average of actual wholesale costs but indeed was something greater than the costs that doctors paid for drugs; right?
- A. Yes. [p. 93].¹¹

Others from BCBSMA confirm his understanding. 12

D. BCBSMA Did Not Have Access To True Data

There is no evidence that BCBSMA, as opposed to its staff model HMO subsidiary Medical West, knew the true cost of the drugs at issue. To the contrary, until 2005 when BCBSMA began looking at materials published by Medicare in preparation for a change to ASP based reimbursement, BCBSMA believed that the AWPs that BCBSMA had been using as a basis for reimbursement was the price at which, on average, physicians were paying to purchase physician-administered drugs. Such an understanding is consistent with Dr. Hartman's expectation theory. *See also* Hartman Class 3 Decl., ¶¶ 25(b), 25(d).

¹¹ Ex. 2 (Mulrey Dep. at 87-88, 93).

 $^{^{12}}$ See, e.g., Declaration of Deborah Devaux in Support of Plaintiffs' Opposition to Track 1 Defendants' Motion for Summary Judgment With Respect to Class 3 ("Devaux Decl."), ¶¶ 10-14 (until 2005, she was unaware of large spreads or that the spreads exceeded 30% of ASP).

And Defendants, after 14 depositions of BCBSMA employees, and the production of tens of thousands of documents, have unearthed not one document showing BCBSMA itself was aware of the true ASPs for these Defendants' drugs or of Defendants' unlawful practice.

E. Given The Pervasiveness Of The AWP Benchmark, BCBSMA Relies On It

In February 2004, sometime after CMS announced that beginning in 2006 Medicare would no longer rely on AWP as a basis for reimbursement of physician administered drugs and would rely instead on ASP, Mr. Mulrey and others at BCBSMA conducted an analysis of the impact on Medicare's new fee schedules using historic utilization data from BCBSMA. Although the analysis conducted indicated that BCBSMA would save a "modest amount of money" if BCBSMA moved to using Medicare's calculated ASP and Medicare's new schedule for administration fees associated with physician administered drugs, the Provider Financial Strategy Work Group made the decision, for now, not to adopt ASP. 14

This decision was made primarily because ASP was not, and still is not, a well-established standard that is widely used and understood industry-wide. It was thought at the time that BCBSMA should not move to the use of ASP until it was clear that Medicare would continue to use ASP and that ASP reached a certain level of acceptance within the industry. Furthermore, members of the Provider Financial Strategy Work Group felt that at the time the savings associated with moving to ASP was offset by the expense in both time and money

¹³ Mulrey Decl., ¶ 12; Devaux Decl., ¶ 10.

¹⁴ Devaux Decl., ¶ 11.

¹⁵ Devaux Decl., ¶¶ 11-13.

necessary to make such a shift, at least until ASP was a more established and accepted standard industry-wide. ¹⁶

This is understandable given the fact that, as Dr. Anderson of Johns Hopkins testified to in *Lupron*, with 65,000 drugs in the marketplace setting different pricing standards on a drug-by-drug basis is impossible, thus fostering the AWP pricing standard.¹⁷ As Dr. Hartman explains,¹⁸ even if a payor had concerns with the fairness of AWP as to one specific drug, payors need a standard and are consequently forced to use one even if aware of instances of abuse with respect to specific drugs.¹⁹

F. There Is No Evidence Other Massachusetts TPPs Knew Of The Spread Game

There is no evidence that class representative Pipefitters or any other Taft-Hartley-type or self-insured union fund was aware of Defendants' scheme. Pipefitters is a perfect example of a typical Taft Hartley fund, operating out of a small space of approximately 1,300 square feet. The staff is likewise very small, with a total of five employees.²⁰

There are approximately 4,600 individuals, both union members and their dependents, who receive major medical benefits, including prescription drug benefits, through the Pipefitter's Fund.²¹ Members of the Pipefitters' Fund are tradesmen and tradeswomen who work on buildings systems, including but not limited to heating ventilation and air conditioning (HVAC)

¹⁶ Devaux Decl., ¶¶ 12.

¹⁷ See also Devaux Decl., ¶¶ 12-13.

¹⁸ See Hartman Class 3 Decl., n.12 (citing Anderson).

¹⁹ Hartman Class 3 Decl., ¶ 13(b).

²⁰ Declaration of Charles Hannaford in Support of Plaintiffs' Opposition to Track 1 Defendants' Motion for Summary Judgment With Respect to Class 3 ("Hannaford Decl."), ¶ 6.

²¹ Hannaford Decl., ¶ 8.

systems. Members of the Union and of the Pipefitter's Fund generally work and live in Eastern Massachusetts.²²

Pipefitters had a small program for retirees through a PBM and had contracted to provide very limited prescription coverage to retirees of up to \$700 per year. The contracted reimbursement paid by the Fund under that program for brand-name drugs was AWP less 18%. The Fund subscribed to the *RedBook* in order to spot check the prices being paid to ensure that the Fund was being charged 18% less than the published average wholesale price.²³

As described by the Fund's Administrator, it was not until approximately March 31, 2003, when he read an article in the *Wall Street Journal* entitled "Hired to Cut Costs, Firms Find Profits in Generic Drugs," that he or members of the Fund's staff came to understand that the published AWPs were inflated and were not the actual average of wholesale prices. Shortly thereafter, he brought this article and the subject matter of AWP inflation to the attention of staff and to members of the Board of Trustees. This was the first time any of them had any indication that the published AWPs were not in fact the average of wholesale prices.²⁴

Further, although that *Wall Street Journal* article concerned discounts off of AWP available to PBMs, it does not identify all of the drugs which are subject to such discounts and does not discuss the role that particular drug companies play in setting the AWP or in marketing the difference between their published AWP and the actual acquisition cost to providers as a means of selling more of their products. "No one at the Fund has ever had any communications

²² Hannaford Decl., ¶ 9.

²³ Hannaford Decl., ¶ 12.

²⁴ Hannaford Decl., ¶ 16.

with any drugs [sic] companies concerning the relationship between AWP and the actual prices at which their drugs are available for purchase by providers."²⁵

As the Pipefitter's Administrator noted:

Despite my awareness of the *Wall Street Journal* article in March of 2003, I still had insufficient information at that time to determine whether the AWPs were inflated over the actual prices being paid by health care providers for these drugs and if inflated, how much that inflation was. The Fund lacks the resources in both time and money to undertake such a wide-ranging and in-depth analysis. Until approached about participation in this lawsuit in the summer of 2005, I feel I did not possess sufficient knowledge or information concerning the nature or extent of the AWP inflation to bring suit. To the best of my knowledge, the Fund could not have discovered the AWP scheme outlined in the complaint in this matter any sooner than it did.²⁶

There is no other evidence in Defendants' motion regarding the knowledge of any other Class 3 payor of the AWP Scheme at issue, and it is obvious that Pipefitters had no such knowledge.

G. HFCA Is An Adequate Representative For The (B)(2) Class

HCFA is a non-profit devoted to health care reform and, in particular, assisting the most vulnerable sectors of society, such as the poor, the young, and the elderly.²⁷ It has been directly involved in programs directed at providing "safety nets" for seniors. Id., ¶ 5. HCFA has 260 organizational members and 900 individual members. Id., ¶ 10. It believes that, given the size and makeup of its members, some are directly affected by the AWP scheme. Id., ¶ 12. And contrary to Defendants' assertion that HCFA became involved only after receiving a grant,

²⁵ Hannaford Decl., ¶ 14.

 $^{^{26}}$ *Id.*, ¶ 17.

²⁷ Declaration of Melissa D. Shannon in Support of Plaintiffs' Opposition to Track 2 Defendants' Motion for Summary Judgment With Respect to Class 3 ("Shannon Decl."), \P 4.

HCFA was a plaintiff in the first complaint filed in this Court and has stayed involved in the litigation from its inception.²⁸

ARGUMENT

I. BCBSMA IS A PROPER CLASS REPRESENTATIVE AND MAKES PAYMENTS BASED ON AWP

Defendants first argue that summary judgment should be granted against BCBSMA because it is not a member of the certified Class. If BCBSMA is not a member of the Class, the remedy is to find BCBSMA not typical and to exclude it from the Class, not to grant summary judgment on liability. The purported failure to meet the Class definition is not a basis for concluding BCBSMA has no claim under Massachusetts law.

Nonetheless, BCBSMA is a typical and proper representative of the Class, and Defendants' motion regarding the Class definition elevates form over substance. Defendants are correct that on its face BCBSMA's contracts do not expressly refer to AWP, and such express reference is part of the Class definition. However, the testimony is undisputed that BCBSMA's fee schedule and its reimbursement policy for physician-administered drugs has since 1995 been based on AWP. *See infra* Section III.B and Mulrey Decl., ¶¶ 8-11. All of its fee schedules are based on AWP, and its claims data permits identification of any unusual fee arrangements not based on AWP. Thus, it is at best a technicality that there is no express reference to AWP in the BCBSMA contracts. The fact is BCBSMA does pay based on AWP.

²⁸ Shannon Decl. ¶¶ 7-8.

²⁹ Mulrey Decl., ¶ 11, noting that it is possible to use BCBSMA's electronic claim data to identify transactions that are not based upon AWP: "On the TPS claim segment HM screen the claim payment element would show a value of 'OS,' which indicates the claim was a capitated claim."

³⁰ Rather than grant summary judgment or deem BCBSMA not a member of the Class the Court should deem BCBSMA as a proper Class member or should modify the Class definition to allow for Class membership to include those either whose fee schedules or payment policies were also based on AWP.

In a complete contradiction of their assertion, Defendants elsewhere argue that BCBSMA is so smitten with AWP as a reimbursement benchmark that BCBSMA continues to use it:

BCBSMA has purposefully chosen to continue using AWP ... [It] is admittedly satisfied with its use of AWP as a reimbursement benchmark.... In fact, BCBSMA is so enamored with AWP that it is currently in the process of extending its use of AWP... [Defs. Br. at 11.]

Defendants cannot have it both ways, claiming that BCBSMA is "enamored" with its use of AWP and then turning around and claiming BCBSMA is not a Class member because its payments are not based on AWP. Such gamesmanship should be rejected.

II. HEALTH CARE FOR ALL HAS STANDING TO SUE

Falsely claiming that Health Care For All ("HCFA") "knows nothing about this suit" and that none of its members were injured, Defendants argue that HCFA does not have standing.

Defs. Br. at 24, 29-30. To support this argument, Defendants selectively and misleadingly cite from the Shannon transcript (HCFA's witness) and otherwise misapply the law.

To satisfy Article III's standing requirements, a plaintiff must show (i) an injury in fact, (ii) a causal relationship between the injury and the challenged conduct, and (iii) a likelihood that the injury will be redressed by a favorable decision. *See*, *e.g.*, *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC)*, 528 U.S. 167, 180-81 (2000) (finding plaintiffs satisfied associational standing test). "It is well settled that, under certain circumstances, an unincorporated association may premise standing upon injuries suffered by some or all of its members." *United States v. AVX Corp.*, 962 F.2d 108, 116 (1st Cir. 1992). Under the doctrine of associational standing, an organization may sue to redress its members' injuries, even without a showing of injury to the organization itself, where: (i) its members would otherwise have standing to sue in their own right; (ii) the interests it seeks to protect are germane to the

organization's purpose; and (iii) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 79 (D. Mass. 2005) ("In re AWP") (Saris, J.) (citing United Food & Commercial Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 553 (1996) (quoting Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977)). Courts routinely find that associations readily satisfy all three prongs. See, e.g., Interfaith Cmty. Org. v. Honeywell Int'l., Inc., 399 F.3d 248 (3d Cir.) (holding that community organization established associational standing in citizen suit where individual members of the association had standing based on their concerns over health risks caused by waste from former site of manufacturing plant, and interests at stake were germane to organization's purpose, which included improvement of quality of life in area where all of the individual plaintiffs lived and the site was located), cert. denied, ____ U.S. _____, 125 S. Ct. 2951 (2005); Defenders of Wildlife v. United States EPA, 420 F.3d 946, 956-58 (9th Cir. 2005) (finding that public interest groups had standing to challenge EPA decision to transfer Clean Water Act pollution permitting program for Arizona where individual members of groups resided in affected areas, had a personal interest in protecting listed species that might be adversely affected and alleged injuries would be redressable by a court order vacating or mitigating the transfer decision); American Library Ass'n v. FCC, 406 F.3d 689 (D.C. Cir. 2005) (finding library association plaintiffs satisfied three-part associational standing test). Indeed, this Court has already held that association Plaintiffs could press any class claims for non-monetary relief under Fed. R. Civ. P. 23(b)(2). In re AWP, 230 F.R.D. at 80.

HCFA has proper standing to seek injunctive relief. HCFA is committed to providing seniors with access to affordable drugs, has 260 organizational members and 900 individual

members, and thus believes given the size and makeup of its membership that its members are affected by the AWP scheme.³¹

III. DEFENDANTS' UNFAIR AND DECEPTIVE ACTS AND PRACTICES CAUSED DAMAGE TO ALL CLASS 3 TPPs

Defendants begin their argument by asserting that no one was deceived by their conduct and/or that there was no causal connection between inflated AWPs and Class members' payments. This argument is almost entirely premised on a misleading portrayal of BCBSMA's actions. Consequently, Defendants' motion has no viability as to BCBSMA or for any other member of the Class. Importantly, Defendants' motion, which is predicated largely on the so-called "knowledge" issue, must first be placed in the context of the elements of a § 93A claim and the constellation of facts relating to Defendants' practices.

A. Defendants' Unfair And Deceptive Acts And Practices Have Damaged Payors

1. Defendants published or caused to be published AWPs

First, the lynchpin of this case is Defendants' creation and assistance in establishing AWP as a reimbursement benchmark. The Court has already agreed, finding that "[t]he AWP, or its formulaic equivalent the WAC (Wholesale Acquisition Cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs." *In re AWP*, 230 F.R.D. at 68 (quoting Hartman at 3).³² And as Dr. Hartman has described:

[A]s a matter of economics, list prices are some of the most important signals that all drug manufacturers, particularly innovator drug manufacturers, use to strategically place drug products in the market. The two most important list prices are the

³¹ Shannon Decl., ¶ 12. And, HCFA has shown a continuing interest in this litigation, and has monitored the case since its inception. Id., ¶¶ 7-8. The grant given HCFA was thus independent of any decision to become involved and was awarded solely to defray the costs of locating individuals who made a Medicare Part B copayment to satisfy the Court's order regarding Class 1. Id., ¶ 9.

 $^{^{32}}$ So, too does, Dr. Berndt (Berndt Report at 6) and even Mr. Young (Oct. 25, 2004 Young Rebuttal Report at ¶ 134).

AWP and the WAC (or WLP).... Since there is a well understood formulaic relationship between AWP and WAC, ... reporting *either* to the price reporting services implies that *the other list price is set automatically*. ³³

2. The publication of phony AWPs is a violation of 93A

Disseminating list prices, or in this case AWPs, when fully aware that list prices are not the usual and customary prices at which the products are sold constitutes unfair and deceptive practices under the Federal Trade Commission Act. *See Matter of Regina Corp.*, 61 F.T.C. 983, 1962 F.T.C. Lexis 92, at *34-36 (Oct. 11, 1962) (citing cases). Indeed, the Commission has explained that, while establishment of list prices is not necessarily unlawful, "a legal practice may not be used to accomplish an illegal objective." *Id.*, at *8. The Massachusetts Attorney General's regulations are in accord. They provide that "[n]o claim or representation shall be made by any means which has the capacity or tendency or effect of deceiving buyers or prospective buyers as to the value of the past, present, common or usual price of a product, or as to any reduction in price of a product...." 940 Ma. Admin. § 3.16. [I]t is settled that "[o]ne who places in the hands of another a means of consummating a fraud or competing unfairly in violation of the [FTC] Act is himself guilty of a violation of the Act. Proof of petitioner's intention to deceive is not a prerequisite to a finding of a violation...; it is sufficient that

 $^{^{33}}$ Hartman S.J. Opp., ¶ 27 (footnotes omitted; emphasis added); *see also* Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification ("Hartman Class Cert. Decl."), Attachment D, ¶ 1 (explaining that AWP and WAC are "interchangeable" since "the two list prices are usually related by a constant ratio [and] convey the same information to purchasers and other entities that rely on published price data").

³⁴ Chapter 93A directs courts "to consider the interpretations of unfair acts and practices under § 5 of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (1970), as construed by the Federal Trade Commission and the Federal courts." *PMP Assoc., Inc. v. Globe Newspaper Co.*, 366 Mass. 593, 321 N.E.2d 915, 917 (1975); *accord*, 940 Ma. Admin. § 3.16.

³⁵ AG rules and regulations, including those relating to Chapter 93A, "unless invalid, have the force of law." *Homsi v. C.H. Babb Co.*, 10 Mass. App. Ct. 474, 479, 409 N.E.2d 219, 224 (1980) (citation omitted).

deception is possible." *Regina Corp. v. FTC*, 322 F.2d 765, 768 (3d Cir. 1963) (citations omitted).

At issue in *Regina* were fictitious list prices supplied by a manufacturer to "distributors and retailers, thereby representing, directly or indirectly or by implication, that such 'list' prices are the usual and customary retail prices for such merchandise," 1962 F.T.C. Lexis 92, at *2. This violated the FTC Act:

Misrepresentations of the usual and customary value of a product and of savings afforded by an offered sale price of such product are unfair and deceptive practices under the Federal Trade Commission Act. . . . In this case, Regina disseminated its suggested list prices to resellers rather than directly to the purchasing public. Regina was fully aware that these suggested list prices were not the usual and customary retail prices at which Regina products were sold in the trading areas involved. In so furnishing fictitious retail prices to resellers, Regina placed in the hands of retailers and others the means and instrumentalities by which they could mislead and deceive the purchasing public. Such practice is a violation of the Federal Trade Commission Act.

Id., at *34-36 (citations omitted). See also Niresk Indus., Inc. v. FTC, 278 F.2d 337, 340 (7th Cir. 1960) ("Misrepresentations of the regular and customary value of a product offered for sale and of savings afforded by an offered sale price of such product are unfair and deceptive practices as defined by the Act."). As one court has explained:

Fictitious prices are illegal even though it is obvious to the sophisticated that the price tag is only a come-on. "The law is not made for the protection of experts, but for the public – that vast multitude which includes the ignorant, the unthinking and the credulous, who, in making purchases, do not stop to analyze, but are governed by appearances and general impressions."

Helbros Watch Co. v. FTC, 310 F.2d 868, 870 n.4 (D.C. Cir. 1962) (citations omitted).

³⁶ The defense argued that benefits flow from its list prices, including providing guidance to financing institutions and to retailers determining product value. But the Commission found that any such benefits cannot justify the dissemination of the fictitious prices. *Id.*, at *36.

Regina is not the only authority prohibiting Defendants' conduct. It is axiomatic under statutes prohibiting misrepresentations that "a party who discloses partial information that may be misleading has a duty to reveal all the material facts he knows to avoid deceiving the other party." V.H.S. Realty, Inc. v. Texaco, Inc., 757 F.2d 411, 414 (1st Cir. 1985); see also Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987) (RICO and securities claims). Indeed, the First Circuit has specifically held that "[w]hen a corporation does make a disclosure – whether it be voluntary or required – there is a duty to make it complete and accurate." Roeder, 814 F.2d at 26 (emphasis added). "Fragmentary information may be as misleading . . . as active misrepresentation, and half-truths may be as actionable as whole lies " V.H.S. Realty, 757 F.2d at 414-15 (quoting *Kannavos v. Annino*, 356 Mass. 42, 48, 247 N.E.2d 708 (1969)). Thus, if a drug manufacturer "chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole truth." Roeder, 814 F.2d at 26 (quoting Grossman v. Waste Mgmt., Inc., 589 F. Supp. 395, 409 (N.D. Ill. 1984)); see also, e.g., Ragsdale v. Kennedy, 286 N.C. 130, 139-40, 209 S.E.2d 494, 501 (1974) ("The rule is that even though a vendor may have no duty to speak under the circumstances, nevertheless if he does assume to speak he must make a full and fair disclosure as to the matters he discusses."); Underwood v. Risman, 414 Mass. 96, 99, 605 N.E.2d 832 (1993) ("A duty exists under c. 93A to disclose material facts known to a party at the time of a transaction.") (citations omitted). Furthermore, as the First Circuit explained in St.-Gobain Indus. Ceramics, Inc. v. Wellons, Inc., 246 F.3d 64, 73 (1st Cir 2001), the methods, acts, and practices deployed by a defendant must be assessed "in their factual setting," id. (citations omitted), not in terms of some cynical parsing of the overall scheme. See also id. at 73 (in interpreting ch. 93A "[w]e focus on the nature of the challenged

conduct and on the purpose and effect of that conduct as the crucial factors in making a G.L. 93A fairness determination'") (citations omitted).

Properly applying Chapter 93A jurisprudence here demonstrates that the course of conduct perpetrated as outlined above is both unfair and deceptive.³⁷

a. Defendants have committed unfair acts and practices in violation of G.L. Ch. 93A

An unfair act or practice is not amenable to a bounded definition because, as courts have recognized, "[i]t is impossible to frame definitions which embrace all unfair practices. There is no limit to human inventiveness in this field." *Levings v. Forbes & Wallace, Inc.*, 8 Mass. App. Ct. 498, 503, 396 N.E.2d 149 (1979) (quoting H. R. Conf. Rep. No. 1142, 63d Cong., 2d Sess. (1914)). Nonetheless, Massachusetts courts, following federal jurisprudence under the Federal Trade Commission Act, ³⁸ have employed the following factors in evaluating whether conduct is unfair: (i) whether the practice is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (ii) whether it is immoral, unethical, oppressive or unscrupulous; and (iii) whether it causes substantial injury to consumers, competitors or other business people. *PMP Assocs., Inc. v. Globe Newspaper Co.*, 366 Mass. at 596 (citing *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972)).

"Whether a given practice runs afoul of these touchstones must be determined from the circumstances of each case." *Levings*, 8 Mass. App. Ct. at 504, 396 N.E.2d 149. In doing so, courts evaluate the "equities between the parties," and "[w]hat a defendant knew or should have

³⁷ Although Defendants' conduct is both unfair and deceptive, the Court need not find the presence of both in order to find that Defendants violated G.L. Ch. 93A. For example, a practice can be *unfair* without being deceptive. *See*, *e.g.*, *Service Publications*, *Inc.* v. *Goverman*, 396 Mass. 567, 578, 487 N.E.2d 520 (1986).

³⁸ Courts are to be guided by interpretations given by the Federal Trade Commission and federal courts to section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1). *Slaney v. Westwood Auto, Inc.*, 366 Mass. 688, 694, 322 N.E.2d 768 (1975).

known may be relevant" in making that determination. *Swanson v. Bankers Life Co.*, 389 Mass. 345, 349, 450 N.E.2d 577 (1983). The Court is to "focus on the nature of challenged conduct and on the purpose and effect of that conduct as the crucial factors in making a G. L. c. 93A fairness determination." *Massachusetts Employers Ins. Exch. v. Propac-Mass, Inc.*, 420 Mass. 39, 43, 648 N.E.2d 435 (1995).

Defendants' acts and practices are unfair. First, each Defendant perpetuated the publication of inflated AWPs while knowing full well that those same AWPs constituted the reimbursement benchmark, manipulated spreads between AWPs and actual costs, and took concrete steps to market those spreads to providers. Each of these actions readily falls within the penumbra of common-law, statutory, or other established concepts of unfairness, particularly given the OIG's admonitions that: (i) AWP must be a meaningful figure that is not artificially inflated; (ii) the "government sets reimbursement with the expectation that the data provided are complete and accurate" and include various price reductions; and (iii) it is illegal for a manufacturer to knowingly establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

Second, that same conduct is immoral, unethical, oppressive or unscrupulous. It rises to a "level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce." *Levings*, 8 Mass. App. Ct. at 504, 396 N.E.2d 149. Or, as another court has waxed, it leaves a "rancid flavor of unfairness." *Propac-Mass, Inc.*, 420 Mass. at 43, 648 N.E.2d 435 (quoting *Atkinson v. Rosenthal*, 33 Mass. App. Ct. 219, 226, 598 N.E.2d 666 (1992)). And although it perpetrated such conduct, even Defendants themselves recognized that manipulating and marketing spreads was unethical or wrong. *See*, *e.g.*, Ex. 3, Jan. 26, 2001, BMS/AWP/000192876 (BMS Memo acknowledging that "the spread should not be used as a

promotional or marketing tool"); Ex. 4 (Schultz Dep. II at 93-95, 124-29 (AstraZeneca Pricing Strategy Manager, Erik Schultz, explained that he thought it was "sleazy" and "an ethical problem" for AstraZeneca to evaluate and increase the AWPs for Zoladex based on whether physicians were making enough profit)); Ex. 5 (Levonyak Dep. at 80-81, 91-93, 214-18 (Kytril Sales Director explaining how SKB sales force discussed spread issues with customers, then were prohibited from doing so, and then were authorized to discuss in a nuanced manner)); Ex. 6 (Glassco Dep. at 113-14 (Centocor's National Accounts Manager and Regional Business Director instructing employees to stop talking to physicians about profit)). There should be no debate that gouging payors is immoral, unethical, oppressive and unscrupulous.

b. Defendants have committed deceptive acts and practices in violation of G.L. Ch. 93A

An act or practice is deceptive if it possesses a tendency to deceive. *Leardi v. Brown*, 394 Mass. 151, 156, 474 N.E.2d 1094 (1985). *See also* 940 C.M.R. § 3.04 ("No claim or representation shall be made by any means which has the capacity or tendency or effect of deceiving buyers or prospective buyers as to the value or the past, present, common or usual price of a product, or as to any reduction in price of a product, or any saving relating to a product."); 940 C.M.R. § 3.05(1) ("No claim or representation shall be made by any means concerning a product which directly, or by implication, or by failure to adequately disclose additional relevant information, has the capacity or tendency or effect of deceiving buyers or prospective buyers in any material respect."). ³⁹

"In determining whether an act or practice is deceptive, 'regard must be had, not to fine spun distinctions and arguments that may be made in excuse, but to the effect which it might

³⁹ These Attorney General regulations have the force of law, and violations of them constitute violations of G.L. ch. 93A. *Purity Supreme, Inc. v. Attorney Gen.*, 380 Mass. 762, 775, 407 N.E.2d 297 (1980).

reasonably be expected to have upon the general public." *Leardi*, 394 Mass. at 156, 474 N.E.2d 1094 (quoting *P. Lorillard Co. v. FTC*, 186 F.2d 52, 58 (4th Cir. 1950)). The plaintiff need not prove that the defendant intended to deceive the plaintiff. *Aspinall v. Philip Morris Cos., Inc.*, 442 Mass. 381, 394, 813 N.E.2d 476 (2004). Nor is proof of reliance required as long as there is a causal relationship between the act or practice and injury to the plaintiff. *Fraser Eng'g Co., Inc. v. Desmond*, 26 Mass. App. Ct. 99, 104, 524 N.E. 2d 110 (1988).

Defendants' course of conduct was deceptive as a matter of law, as the tendency or capacity to deceive is plainly present. The deliberate decision to report list prices or AWPs to national pharmaceutical industry publications with knowledge of how they would be marked up to result in AWPs – *knowing that these published AWPs would form the basis of an industry-wide reimbursement system* – obligated Defendants by law to ensure that these pricing benchmarks were *not* misleading. *V.H.S. Realty*, 757 F.2d at 414; *Roeder*, 814 F.2d at 26.

Moreover, as the evidence demonstrates, each Defendant enacted a concerted scheme to manipulate spreads on their Subject Drugs and then market those spreads. "[T]he effect [that this] might reasonably be expected to have upon the general public," *Leardi*, 394 Mass. at 156, 474 N.E.2d 1094, is obvious: consumers and TPPs have become obligated to make inflated payments for Subject Drugs as a direct and proximate result of AWP manipulation, and at no fault of their own. This highlights the insidiousness of Defendants' actions and weighs heavily in favor of finding that the acts and practices had the capacity to deceive.

3. Class members were in fact deceived

Although the main thrust of Defendants' motion is that no one was deceived, the evidence is to the contrary. Charles Hannaford, Pipefitter's Fund Administrator, testified that the Fund used AWP, tried to check its accuracy and was unaware until 2003 that AWPs were not the

actual average. Hannaford Decl., ¶ 13. It is hard to imagine how Defendants can claim Pipefitters was not deceived.

Further, BCBSMA was also deceived. As Mr. Mulrey of BCBSMA testified:

Until I began looking at materials published by Medicare in preparation for the analysis I conducted in February 2004 concerning the impact of a move from the use of AWP to ASP, I believed that the AWPs that BCBSMA had been using as a basis for reimbursement was the price at which, on average, physicians were paying to purchase physician administered drugs.

I was not aware that the AWPs which BCBSMA used to establish its fee schedules for physician administered drugs may have been inflated and may not have borne a reasonable or predictable relationship to the actual prices being paid by physicians for these drugs. 40

4. Causation is established

Had Defendants reported accurate pricing information, the prices reported would have been lower as would AWP based payments. Had Defendants not engaged in manipulation of spreads, Medicare reimbursement and private reimbursement and co-pays based thereon would have been lower. Class members would have paid less because, in the absence of concealment of the actual prices and Defendants' gaming, inflated billings could not have been sustained. Dr. Hartman explains this at great length in his Liability Report (Ex. 1). Furthermore, in deciding Defendants' motions to dismiss, the Court already considered and rejected Defendants' lack of causation arguments, finding that they were "not persuasive" and that the harm incurred was direct:

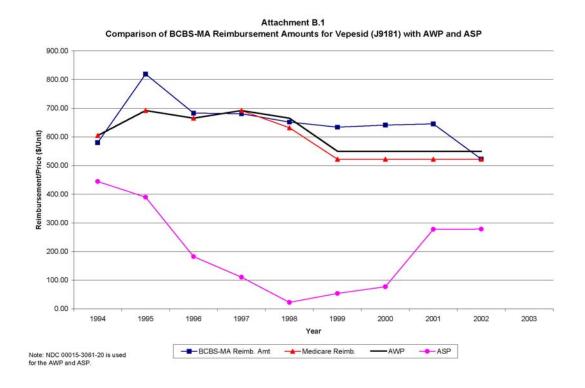
In the private, end-payor context, the harm alleged by Defendants' alleged actions is visited directly upon the end-payor Plaintiffs, as they have paid directly for the named drugs based on the AWP's. Similar arguments about intervening causes

⁴⁰ Mulrey Decl., ¶¶ 14-15.

between the setting of an AWP by a defendant and injuries to plans and individual co-payors were recently rejected [by Judge Stearns] as "bordering on the frivolous."

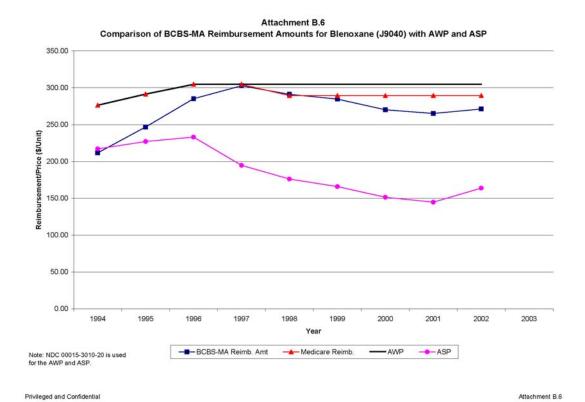
In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196, 207 (D. Mass. 2004) (quoting Lupron, 295 F. Supp. 2d at 175) (emphasis added).

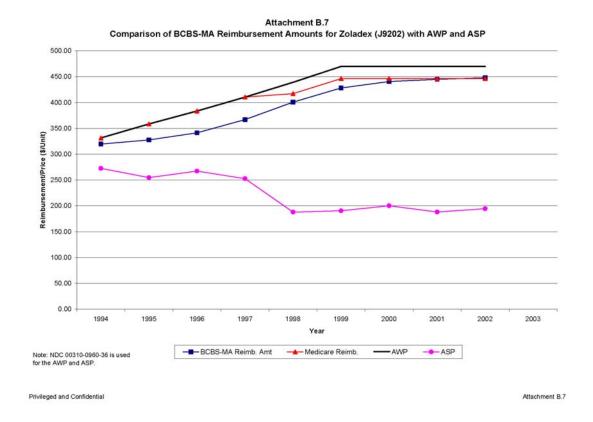
There is also no dispute that Class members such as Pipefitters and BCBSMA based their payments on AWP. And there is no dispute that the AWPs were (i) not a real average and (ii) were for the Subject Drugs not within any reasonable bounds of an average. There is no dispute that the drug industry knew AWP was the basis for payment. There is no dispute that each of the Defendants created spreads that rendered the published AWPs misleading. For example, the following graphs show the published AWP, the BCBSMA price for the drug which closely tracks AWP and the spread created by ASP for two BMS drugs and one drug made by AstraZeneca:



Attachment B.1

Privileged and Confidential





Thus, the foregoing illustrates the impact of payment based on AWP upon Class members, *i.e.*, it was substantially inflated over the ASP.

Defendants' contention that publication of inflated AWPs is not a deceptive practice and not a cause of Class injury was rejected by Judge Stearns, who distinguished several of the cases Defendants rely upon and explained:

A good argument can go wrong when its fundamental premise is flawed. It is true, as defendants contend, that no federal case or statute imposes a duty on a manufacturer to disclose to retail consumers the prices that it charges intermediate suppliers for its products, nor with a possible antitrust exception, is a seller required to charge the same price for a product to every consumer in every market. This is true even where the seller derives a presumed benefit from the consumer's ignorance of what it

actually paid for the products it sells. See Alves v. Harvard Pilgrim Health Care, Inc., 204 F. Supp. 2d. 198, 212-14 (D. Mass. 2002) (Saris, J.), aff'd, 316 F.3d 290 (1st Cir. 2003). . . . But this is not a case of nondisclosure. Defendants did not stand mute. [D]efendants trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud. Whether one views the defendants' actions as involving the dissemination of information that was wholly false, or false because of an incomplete depiction of the truth, they are actionable under the mail and wire fraud statutes. . . . This is not a case of a retailer failing to disclose the discounted prices that it offered to favored customers (Langford), or a manufacturer the price differentials on its sales of the same product in different markets (Bonilla), or a health plan the discounts it received on prescription drugs (Alves). Rather, this is a case of affirmative misrepresentation. And because the alleged misrepresentations were knowing, deliberate, and made in furtherance of a scheme to defraud, they are sufficient to support the predicate acts of mail and wire fraud.

In re Lupron Mktg. & Sales Practices Litig., 295 F. Supp. 2d 148, 167-68 (D. Mass. 2003) (footnote omitted)).

In sum, Defendants' deliberate decision to report pricing information to publications, coupled with a thorough awareness of how AWPs were derived from their prices and that published AWPs would form the basis of an industry-wide reimbursement system, obligated Defendants by law to ensure that these pricing benchmarks were not misleading.

5. BCBSMA can establish causation

Defendants claim that BCBS knew that AWP did not bear any relationship to an average and therefore was not deceived and/or subjected to unfair practices. Defs. Br. at 33. The facts are to the contrary.

BCBSMA witnesses have testified that they believed AWP was an average⁴¹ and that it bore a predictable relationship to actual prices.⁴² Indeed, Mr. Fox testified precisely to the causative effect of Defendants' practices. As he put it, the difference between a sticker price and the invoice price on a car provides a basis for comparison. Similarly, he believed AWP was related to invoices and that if "we thought there was an unrealistic set between that and some other price, we would have discounted by some other number. . . ." Ex. 10 (Fox Dep. at 131).

To avoid this obvious reliance and causation testimony, Defendants claim that since BCBSMA did not switch to an ASP based methodology in 2004-2005, there is no damage or element of unfairness. Of course, BCBSMA's decision has nothing to do with lack of deception, unfairness or causation prior to 2004. And, as explained above, given the prevalence of AWP as an industry standard, it is virtually impossible to negotiate prices on an individual basis. *See* Hartman Class 3 Decl., ¶ 12. Furthermore, BCBSMA's decision to stay with AWP was based upon the fact that AWP was the industry standard, and the costs created by switching from this standard, as well as the uncertainty, resulted in a decision to stay with AWP for now. And the inference to be drawn in Plaintiffs' favor on this motion are that the Defendants knew it was difficult for payors to switch out of the AWP system and thus continued to publish phony AWPs. This certainly is an unfair practice that caused damages to Plaintiffs and the Class.

Defendants' arguments as to purported knowledge by other TPPs is based upon the same analysis of staff-HMO purchases Gaier did earlier in the year. In his April declaration,

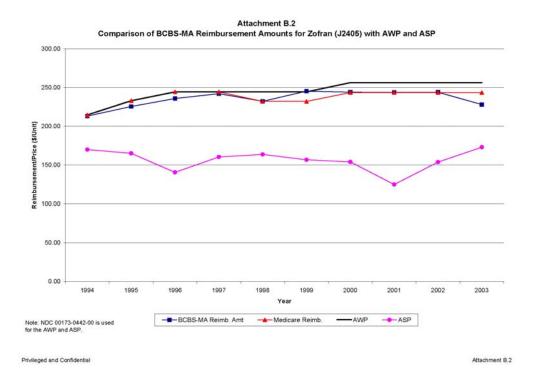
Dr. Hartman pointed out that an analysis of BCBSMA data, as opposed to data from a separate

⁴¹ Ex. 7 (Cook Dep. at 133:21-134:19; Ex. 2 (Mulrey Dep. 79:14-20); Ex. 8 (O'Brien Dep. 39:17-40:5).

⁴² Ex. 9 (Devaux Dep. 224:6-17); Ex. 10 (Fox Dep. 131; 175-76).

⁴³ Devaux Decl., ¶¶ 12-13.

disbanded subsidiary, indicates BCBSMA's payment tracked AWP, not ASP. Defendants and Dr. Gaier had six months to respond to Dr. Hartman and analyze BCBSMA data, as opposed to data from the disbanded staff-HMO. They did not do so, and the reason for the omission is simple: BCBS payment data tracks AWP. *See* Hartman Decl. Class 3, Exhibit B and ¶¶ 11-12. Its payment history confirms lack of knowledge and causation. Thus, for example, its payments for Zoladex track AWP, and one can see how, while AWP was slightly increasing, the actual ASP declined or stayed constant – a graphic representation of causation and lack of knowledge:



Thus, Dr. Gaier's expansive belief that these payors had knowledge is not borne out by the data with respect to BCBSMA, and similar staff-model HMO data from other TPPs should not be the basis for a proposed summary judgment as to an entire class.

6. Medical West's knowledge does not bar BCBSMA's claims

Defendants claim that a staff-model HMO subsidiary of BCBSMA, Medical West, purchased drugs at close to ASP. They argue that Medical West's knowledge of ASPs for the drugs it purchased should be imputed to its parent, BCBSMA. They argue that if this knowledge is imputed to BCBSMA, then the Court must bar BCBSMA from pursuing its claims against them for unfair or deceptive trade practices. They are wrong.

As Plaintiffs have shown in this memorandum and elsewhere, there is no reliance requirement under the Massachusetts consumer fraud statute. *Hershenow v. Enterprise Rent-a-Car Co. of Boston*, 445 Mass. 790, 800, 840 N.E.2d 526, 534 (2006) (Section 93A statutory cause of action is to be distinguished from "a common-law action for deceit and fraud"; with Section 93A claim, "proof of actual reliance by the plaintiff on a representation is *not* required"") (emphasis added) (citations omitted). Thus, Defendants cannot escape the consequences for their illegal behavior by again making the tired argument that Plaintiffs could not possibly have believed that Defendants' bogus AWPs actually denoted average wholesale prices.

What is more, any knowledge on the part of Medical West as to ASPs for certain drugs cannot be imputed to BCBSMA in the first place (let alone to any Class member). Medical West and BCBSMA are separate corporations, notwithstanding their status as subsidiary-parent. Parents and subsidiaries are treated as separate and distinct entities absent some abuse of the corporate form, *Stryker Corp. v. XL Ins. Am., Inc.*, 2006 U.S. Dist. Lexis 47899, at *29 (W.D. Mich. July 14, 2006), and no evidence of abuse of the corporate form exists here. *See also Oei v. Citibank, N.A.*, 957 F. Supp. 492, 519 (S.D.N.Y. 1997) ("Plaintiffs claim that Citibank Int'l's acts and knowledge should be imputed to Citibank because . . . Citibank and Citibank Int'l are

related. However, there is no dispute that in 1992 Castellanos was employed by Citibank Int'l and Citibank Int'l was a wholly-owned subsidiary of Citibank. . . . Plaintiffs have presented no evidence demonstrating that I should pierce the corporate veil and that knowledge of the subsidiary should be imputed to the parent corporation.") (citation omitted); *Doyle v. Bresler's* 33 Flavors, Inc., 1972 U.S. Dist. Lexis 13515, at *2-*3 (N.D. Ill. 1972) ("[K]nowledge of the acts of a subsidiary corporation cannot be imputed to a parent corporation where the subsidiaries are not shown to be either mere agents of the parent or alter egos of the parent[.]") (citation omitted).

Nor is there any allegation, let alone proof, that BCBSMA so dominated and controlled Medical West that knowledge of ASPs on the part of Medical West should be imputed to BCBSMA. *See ISI Sys., Inc. v. Equifax, Inc.*, 1996 U.S. Dist. Lexis 882, at *11 (D. Mass. Jan. 12, 1996). Certainly, for example, there is no evidence whatsoever that Medical West was in any way responsible for BCBSMA's traditional indemnity operations, just as there is no evidence that BCBSMA was responsible for Medical West's staff-model HMO functions. *See id.* (describing one factor to be considered in corporate-domination analysis the court employed as "the parent's and subsidiary's relative responsibility for day-to-day operations"). 44

Furthermore, even if actual reliance were an element of a claim under Section 93A, which it is not, and even if the law permitted imputation of Medical West's supposed knowledge to BCBSMA, which it does not, that imputation to BCBSMA as a general proposition would not suffice to derail Plaintiffs' case. BCBSMA is a large corporation, with different divisions and personnel responsible for different functions. Defendants have adduced no evidence whatsoever that purported knowledge as to ASPs reached the BCBSMA personnel actually responsible for

⁴⁴ See Coney Decl., ¶¶ 6, 11-14.

paying for AWPIDs on behalf of its insureds. Stryker, 2006 U.S. Dist. Lexis 47899, at *26 ("The knowledge possessed by a corporation about a particular thing is the sum total of all the knowledge which its officers and agents, who are authorized and charged with the doing of the particular thing acquire, while acting under and within the scope of their authority.") (emphasis added) (citation omitted); see also Stetson Press, Inc. v. Bunsen Oil Burner Corp., 285 Mass. 291, 293, 189 N.E. 103 (1934) ("It is true, that the knowledge of an agent has often been held the knowledge of the principal. . . . But that principle does not apply unless the agent having the knowledge has within the scope of his authority the matter with respect to which that knowledge is important. . . . ") (emphasis added) (citations omitted). Defendants' imputation theory fails for this reason, too.

B. Any Purported BCBSMA Knowledge Is Not Imputed To Pipefitters Or To Any Other Class Member

Defendants claim that because Pipefitters "relied entirely" on BCBSMA to manage drug reimbursement for its members and beneficiaries, any knowledge that BCBSMA acquired about Defendants' conduct alleged in this litigation should be imputed to Pipefitters. Defs. Br. at 34-35. As described above, BCBSMA did not know that the huge spreads between WAC and AWP were due to Defendants' deliberate manipulation, or the extent of the spreads, or which days were involved, or of Defendants' marketing practices. Therefore, no so-called "knowledge" can be imputed to Pipefitters in the first instance. *See Adams v. Bernard*, 2001 Mass. Super. Lexis 470, at *8 (Mass. Super. Ct. Sept. 5, 2001) ("A duty exists under G.L.c. 93A to disclose material facts known to a party at the time of the transaction. There is no liability for failing to disclose what a person does not know.") (citations omitted) (holding real estate agent's general

knowledge of industry was insufficient to impute knowledge regarding specific real estate transaction where agent had no such knowledge of structural defect).

Even if the Court determines that BCBSMA knew of Defendants' conduct alleged in this litigation, that purported knowledge still cannot be imputed to Pipefitters. First, any knowledge that BCBSMA acquired was, according to Defendants, by virtue of its staff model HMO being a direct purchaser of the Subject Drugs (see Defs. Br. at 3-6). No where in their brief do Defendants claim – because they cannot – that the individuals or division of BCBSMA that administered Pipefitters' pharmaceutical benefits had knowledge of Defendants' fraud. Under Massachusetts law, while *actual* knowledge of an agent may be imputed to a principal, constructive knowledge – such as the knowledge claimed by Defendants here – cannot be imputed to a principal. New England Trust Co. v. Farr, 57 F.2d 103, 110 (1st Cir. 1932) ("This [imputation] rule can apply only to actual knowledge of an agent as distinguished from constructive knowledge. Prior constructive knowledge could not be present in the mind of an agent when acting for another principal, and hence could not be imputed to such principal."). This conclusion is an extension of the rule that a principal is liable only for acts committed by his agent acting within the scope of its employment. United States v. President & Fellows of Harvard College, 323 F. Supp. 2d 151, 192 n.33 (D. Mass. 2004); see also RESTATEMENT (SECOND) OF AGENCY § 272 ("[T]he liability of a principal is affected by the knowledge of an agent concerning a matter as to which he acts within his power to bind the principal . . . "). Therefore, even assuming that BCBSMA had the knowledge Defendants claim, that knowledge cannot be imputed to Pipefitters as a matter of law.⁴⁵

⁴⁵ The cases on which Defendants rely are distinguishable. Neither *Sunrise Props., Inc. v. Bacon, Wilson, Ratner, Cohen, Salvage, Fialky & Fitzgerald, P.C.*, 425 Mass. 63, 679 N.E.2d 540, 543 (1997), *Lawrence Sav. Bank*

In any event, what BCBSMA knew, and hence what Pipefitters knew, is an issue of fact that cannot be resolved on summary judgment. *Velez-Gomez v. SMA Life Assurance Co.*, 8 F.3d 873, 877 (1st Cir. 1993) ("Our summary judgment jurisprudence precludes judicial resolution of genuine issues of material fact. No doubt what [agent] knew about [insured's] medical condition may be hotly contested at trial.") (internal citations omitted). Defendants' motion as to Pipefitters must fail.

IV. THE STATUTE OF LIMITATIONS DOES NOT BAR ANY OF THE CLAIMS OF THE CLASS 3 TPPs

Defendants acknowledge that the Class 3 claims from October 1997 through the present are timely because the original Complaint was filed in October 2001, and the applicable statute of limitation on Mass G.L. 93 claims is four years. Defendants seek summary judgment on all Class 3 claims for transactions prior to October 1997, arguing that such claims are barred by the statute of limitations. But Plaintiffs provide more than ample factual support to prove that (i) the Class 3 claims fall within the "discovery rule" exception to the four year statute of limitations, and (ii) Plaintiffs are entitled to rely on the fraudulent concealment doctrine given that Defendants actively hid the acquisition prices for their products prior to October 1997.

Furthermore, while Defendants seek summary judgment against all of Class 3, their argument references only the alleged knowledge of BCBSMA; they strategically fail to mention the other Plaintiffs – Pipefitters and Health Care For All – as well as other class members, whose

v. Levenson, 59 Mass. App. Ct. 699, 704-05, 797 N.E.2d 485 (2003), nor *In re Bloom*, 222 Mass. 434, 436-37, 111 N.E. 45 (1916), dealt with constructive knowledge imputed to a principal. And Defendants' cases that purportedly stand for the proposition that the Court must grant summary judgment if a plaintiff cannot show that a third party upon whom the plaintiff relied was actually deceived (*see* Defs. Br. at 34) likewise fail because neither of those cases was interpreting Massachusetts law, under which deception is shown by an objective, rather than subjective, standard. *See Aspinall*, 442 Mass. at 394, 813 N.E.2d at 486 (Mass. 2004) ("Whether conduct is deceptive is initially a question of fact, to be answered on an objective basis and not by the subjective measure argued by the defendants.").

claims are not barred by the statute of limitations.

A. Statute Of Limitations Issues Are Generally Not Appropriate For Summary Judgment

The First Circuit has repeatedly held that issues concerning a plaintiff's knowledge of injury, fraudulent concealment, and triggering of the statute of limitations are almost always questions of fact for the jury. *Wolintez v. Berkshire Life Ins. Co.*, 361 F.3d 44, 48 (1st Cir. 2004); *Young v. Lepone*, 305 F.3d 1, 8-9 (1st Cir. 2002).

Indeed, in *Lupron*, Judge Stearns reviewed many of the same materials cited by

Defendants here, including various government reports and the *Barron's* article, and concluded that such evidence was not enough to take the statute of limitations questions away from the jury. *In re Lupron*, 295 F. Supp. 2d at 183-84. As here, the *Lupron* defendants argued that the statute of limitations barred the plaintiffs' claims because the actual sales prices of Lupron were discoverable with reasonable effort, and "there was a generalized awareness that the AWP exceeded the actual acquisition cost for Lupron." *Id.* at 183. The Court, however, observed that the government discovered the true spreads for Lupron only "after prolonged digging with the coercive assistance of a federal grand jury" and that "the doctors who had benefitted from the false billings for free samples of Lupron would have been unlikely volunteers in any effort by plaintiffs to unearth the scheme on their own." *Id.* Therefore, the Court would not resolve the statute of limitations issues against the plaintiffs as a matter of law. *Id.* Importantly, the lawsuits that form this MDL proceeding were filed only after the *Lupron* cases, the first of which was filed in May 2001.

Thus, another Court, examining much of the same evidence offered by Defendants here, concluded that the various government reports were not, as a matter of law, enough for the

plaintiffs to uncover, through reasonable investigation, the actual spread on Lupron; or that the plaintiffs were prohibited from invoking the fraudulent concealment doctrine. The result here should be no different.

B. Sufficient Evidence Exists To Invoke The "Discovery Rule" Exception To The Four Year Statute of Limitations

Massachusetts recognizes a "discovery rule" that tolls the running of the limitations period for claims under Mass. Gen. L. ch. 93A. *Wolinetz*, 361 F.3d at 47 (citing *Int'l Mobiles Corp. v. Corroon & Black/Fairfield & Ellis, Inc.*, 560 N.E.2d 122, 125-26 (1990)). Under the discovery rule, "a cause of action…does not accrue until the plaintiff knew, or in the exercise of reasonable diligence should have known of the factual basis for his cause of action." *Id.* at 47-48 (citing *Patsos v. First Albany Corp.*, 741 N.E.2d 841, 846 (2001)).

To survive a motion for summary judgment on the basis of the discovery rule, Plaintiffs need only demonstrate a "reasonable expectation of proving [at trial] that their suit was timely filed." *Sawyer v. Indevus Pharms., Inc.*, 2004 Mass. Super. Lexis 274, at *32 (Mass. Super. Ct. July 26, 2004) (quoting *Doe v. Creighton*, 786 N.E.2d 1211, 1214 (Mass. 2003)). This is an objective test: "Only if a reasonable person in the plaintiff's position would have been able to discern the harm or the cause of the harm will the cause of action accrue and the limitations period begin to run." *Id.* (quoting *Riley v. Presnell*, 409 Mass. 239, 245, 565 N.E.2d 780 (1991)). The Court, in making this determination, must view the evidence produced and draw all reasonable inferences in a light most favorable to the plaintiff. *Id.* (citing *Labonte v. Hutchins* & *Wheeler*, 678 N.E.2d 853, 859 (Mass. 1997)).

Initially, Defendants do not, and cannot, claim that the members of Class 3 had actual knowledge of the ASPs and spreads for the Subject Drugs. Rather, Defendants ask this Court to

rule, as a matter of law, that a reasonable person in the position of a Class 3 member "should have known" that the spreads on the Subject Drugs were fraudulent. Defs. Br. at 36. The evidence and case law do not support such a finding here.

1. The Court cannot find as a matter of law that Plaintiffs either knew or should have known about Defendants' scheme

Citing a parade of publicly available reports, Defendants proclaim that the undisputed record shows that Massachusetts payors knew or should have known in the exercise of reasonable diligence that AWPs bore no predictable relationship to acquisition costs. Defs. Br. at 39. But the record evidence actually demonstrates the opposite and that confusion reigned in the marketplace; at a minimum, a material issue of fact exists defeating Defendants' claim to summary judgment.

It is important to define exactly what specific knowledge on the part of Plaintiffs is relevant. Plaintiffs do not dispute that there was, throughout the Class Period, a generalized knowledge that the AWP did not directly mirror actual transaction pricing. This is confirmed by the report of Dr. Hartman, whose entire market expectation theory is based on the premise that the private market understood that AWP prices would be within a certain range above actual transaction prices. The documents Defendants rely on do not reveal specific acquisition prices or Average Sale Prices ("ASPs") for the Subject Drugs but, rather, merely indicate that acquisition prices are below AWP. This fact is not in dispute. What Plaintiffs allege that they did not know, and could not have learned, were the actual ASPs paid for the Subject Drugs, or of the specific marketing practices designed to sell the spread at the expense of Class members.

Defendants have testified that their ASP calculations were internal and were never released to the public. *See*, *e.g.*, Ex. 11 (Hiriak Dep. at 252:14-254:17 (only senior management

got ASP info)); Ex. 12 (Brennan Dep. at 31:4-7, 33:5-6 (AZ didn't give actual prices to consumers)). Moreover, there is no suggestion that ASPs, as opposed to a few individual specific sale prices, were generally available to the public or the members of Class 3. Even in the few instances in which Defendants cite a class member's purchase of a Subject Drug at a price below AWP, such an individual purchase does not reveal the overall market of actual transaction prices or the ASP for that drug, nor did it disclose the underlying creation, manipulation and marketing of the spread. And, since the market in general, and Class 3 members specifically, had an understanding that AWP was closely related to, but did not exactly equal actual transition prices, there was no reason for a Class 3 member to become suspicious when it saw an acquisition price below AWP.

Indeed, BCBSMA and Pipefitters believed that published AWPs were accurate pricing signals. As Mr. Mulrey explains:

Until I began looking at materials published by Medicare in preparation for the analysis I conducted in February 2004 concerning the impact of a move from the use of AWP to ASP, I believed that the AWPs that BCBSMA had been using as a basis for reimbursement was the price at which, on average, physicians were paying to purchase physician administered drugs. . . . I was not aware that the AWPs which BCBSMA used to establish its fee schedules for physician administered drugs may have been inflated and may not have borne a reasonable or predictable relationship to the actual prices being paid by physicians for these drugs. [46]

Similarly, BCBSMA representative Devaux testifies that:

Until the PFSWG considered the move to ASP, I was unaware of large spreads between the published AWP and the actual sales prices at which physicians can apparently purchase some of these drugs. I was aware that some physicians, physicians or physician groups with large practices who could buy in greater quantities for instance, may have paid less and other doctors may

⁴⁶ Mulrey Decl. ¶¶ 14-15.

have paid more for the drugs. However, I was not aware that certain drug manufacturers may have been publishing or causing to be published AWPs that exceeded some of their drugs' actual average sales prices by more than 30% and that they may have done so in order to increase their market share for these drugs at the expense of payors like BCBSMA. Even when PFSWG was considering whether to follow Medicare and begin using ASP, I did not know, and the PFSWG members did not otherwise discuss, which drug manufacturers may have been engaged in the inflation of AWP in this way or which drugs were involved. . . . Other than through this litigation, I have not received information about which physician-administered drugs may have had unduly inflated AWPs [47]

Charles Hannaford, the Pipefitters' Administrator, not surprisingly was also not aware of Defendants' scheme and was under the impression, as were Pipefitters staff members, that AWP was in fact the average wholesale cost of a particular drug. The prospect of AWP inflation did not hit Mr. Hannaford's "radar screen" until he read a newspaper article in 2003, and even then still had insufficient information to determine whether the AWPs were inflated and to what extent.⁴⁸

Thus, the purportedly publicly available reports cited by Defendants were not seen by Plaintiffs. But even had Plaintiffs reviewed them, those reports would have meant little to them. As Dr. Hartman notes, Defendants' parade of public studies, and particularly the OIG studies, focus on self-administered drugs and not physician-administered drugs. Hartman S.J. Opp., Part II.C.a, ¶ 11, pp. 7-9. Moreover, the primary OIG reports cited by Defendants conclude, for the limited sampling of brand name drugs studied, that discounts below AWP ranged from 10 to 20 percent. This is, of course, a far cry from the huge spreads calculated by Dr. Hartman for

⁴⁷ Devaux Decl. ¶¶ 14-15.

⁴⁸ Hannaford Decl. ¶¶ 12-17.

⁴⁹ Apr. 7, 2006 Response of Class Plaintiffs to Statement of Undisputed Facts at ¶¶ 4-6.

Defendants' Subject Drugs and falls well within Dr. Hartman's 30% acceptable "yardstick." In particular, of the few studies that focus on physician-administered drugs, the 1992 OIG report and the 2001 ASCO survey on chemotherapy drugs found spreads within Dr. Hartman's liability yardstick. Hartman S.J. Opp., Part II.C., ¶ 11(b), p. 8. Indeed, after reviewing some 33 studies identified by Dr. Addanki in his declaration in support of the Schering-Plough summary-judgment motion against Classes 1 and 2, Dr. Hartman "conclude[s] that the publicly available survey evidence informing 'the government, policy makers, and industry participants' . . . about spreads on physician administered drugs over much of the damage period suggested that those spreads were not excessive." Hartman S.J. Opp., Part II.C., ¶ 11(d), p. 9.

Similarly, the *Barron's* article from 1996, which Defendants trumpet, does not inform the analysis. First, no Plaintiff saw it. Second, that article merely identified the fact that transaction prices for certain drugs were below AWP; it did not reveal ASP prices. Further, as detailed above, BCBSMA was not aware of the actual ASPs on any of the Subject Drugs. Therefore, its knowledge could not have triggered any applicable statue of limitations for itself or any class members.

Further belying Defendants' assertions that market players should have known in the exercise of reasonable diligence that AWPs bore no predictable relationship to acquisition costs is Dr. Berndt's observation of the "importance of being unimportant," as summarized by Dr. Hartman:

Dr. Ernst Berndt has examined drug cost growth during the 1990s, as managed care became more aggressive in implementing and using practices and procedures to minimize cost. During that period, payors sequentially focused their cost saving efforts, not surprisingly, on the largest cost items, which are physician services, hospital care and "all other" costs. Over the period 1990-1998 (the last year for which Dr. Berndt presents data),

prescription drug costs constituted the least important cost borne by managed care, ranging from 5.4% of total health care expenditures in 1990 to 7.9% in 1998. Dr. Berndt concludes that the overall cost of prescription drugs has continued to grow over this period because of the "importance of being unimportant." Specifically, because drug spending was the least important cost item to managed care, on an absolute and percentage basis, it received the least attention. Therefore, fraudulent pricing practices would be least likely to be detected in prescription drug reimbursement.

Dec. 16, 2004 Hartman Class Cert. Decl. at ¶ 57(c); *see also id.* at ¶ 69 (further discussing Berndt and why even sophisticated economic entities are still bound by the degree to which they can process information in order to implement strategic plans to initiate rational economic behavior, thereby leading them to focus initial efforts on economic decisions that are most pressing); Hartman S.J. Opp. at ¶ 13(a).

The foregoing demonstrates that, for most of the Class Period, there was confusion regarding true prices in the marketplace for physician-administered drugs. Dr. Hartman perhaps best summarizes the historical uncertainty regarding the true costs of physician-administered drugs:

While hindsight, illuminated through discovery in this litigation and other litigation, . . . demonstrates that the substantial spreads found with generic self-administered drugs in the late 1990s were indeed reflected in spreads for physician-administered drugs, *such a general understanding simply did not exist at that time*. No consistent survey information supported such an understanding. Anectodtal information for individual Part B drugs were not sufficient to change the overall expectation throughout the 1990s that the AWP provided *a reasonable expectation* for the EAC of Part B drugs.

Hartman S.J. Opp., Part II.C., ¶ 11(i), p. 10. Far from supporting Defendants' "everyone knew" defense, the evidence reveals that reliable information about true margins was simply not

available or understood. Moreover, the evidence demonstrates that, until very recently, no one knew about Defendants' concealed efforts to manipulate and market spreads.⁵⁰

Under Defendants' logic, Plaintiffs could have learned the true spreads and ASPs for the Subject Drugs if they had made a reasonable investigation. But the evidence indicates that any "investigation" would not have revealed the truth. As they have from the start of the litigation, Defendants cite to not one report that gave an approximation of the true spreads or of the unlawful marketing practice that created these spreads. For example, AstraZeneca's spread on Zoladex, a cancer drug, exceeded 130% from 1991 forward. BMS had spreads on Vepesid 1GM/50ML that started at 41.7% in 1993 and grew to 687.0% by 2000. BMS's spread on Cytoxan 200mg grew from 54.9% in 1994 to 285.3% by 1999. GSK's Zofran had spreads exceeding 50% on some NDCs. Was pread on Remicade, which had a published AWP of over \$600 per pack, was consistently over 30% providing physicians with huge profits. And Schering was in outer orbit on its spreads, with Albuterol going from 142% in 1993 to 1535.4% in 2002. And, there is nothing in the so-called publicly available reports that evidence for example, that Schering was telling doctors that as a result of its spreads "one patient on Intron can represent \$16,956.36 of incremental sales and \$2,373.84 of profit for our physicians just on

⁵⁰ See Mulrey Decl., ¶¶ 14-15 (not aware of potential issues until 2004); Hannaford Decl., ¶¶ 13-16 (not aware of potential issues until 2004).

⁵¹ Ex. 1 (Hartman Liab. Report at G.1.c.).

⁵² *Id.* at G.2.c.

⁵³ *Id.* at G.3.c.

⁵⁴ *Id.* at G.4.c.

⁵⁵ *Id.* at G.5.c. for NDC (50006).

the drug alone."⁵⁶ And there is nothing in the public documents indicating that Schering was paying doctors \$500 per patient under the table for getting them started on Intron-A or Temodar.

2. Discovery Rule Jurisprudence Supports Plaintiffs

The case law supports Plaintiffs and not Defendants. For example, the court in *Sawyer*, in denying the defendants' motion for summary judgment on the basis of statute of limitations, found that the wide-spread public information available to plaintiffs about the withdrawal of diet drugs from the market failed to alert them specifically to the steps necessary to uncover their harm, and therefore, was not sufficient to determine, as a matter of law, that plaintiffs should have known of their injuries. 2004 Mass. Super. Lexis 274, at *49. Publicity of the diet drug epidemic ranged from the major news outlets, including *The New York Times, USA Today, The Boston Herald, The Boston Globe*, "NBC Nightly News" and the "CBS Evening News," to 18,000 lawsuits and 100 putative class actions filed across the country. The *Sawyer* Court, however, could not find a "single public report that would have put [d]iet [d]rug users on notice that an echocardiogram was necessary to diagnose [d]iet [d]rug induced heart disease." *Id.*, at *13.

Thompson v. Metropolitan Life Ins. Co., 149 F. Supp. 2d 38, 50-53 (S.D.N.Y. 2001), provides another example. There, the court reviewed evidence alleged to show the class's knowledge of the overpriced life insurance at issue: 24 news articles over 60 years (including stories in *Time* magazine and *The Wall Street Journal*); an FTC Study; two prior individual lawsuits based on the same claims; and a segment on 60 Minutes. The court concluded that this publicity was insufficient to find on summary judgment that the plaintiffs should have discovered their claims earlier. *Id.* at 50-53.

⁵⁶ Ex. 13.

Similarly, there is no report, investigation, or study that would have indicated or revealed to Plaintiffs here that Defendants were fraudulently reporting an inflated AWP, and in turn, marketing the resulting spread to physicians and pharmacists. Defendants' motion must be denied.

Defendants' reliance on public records cases such as Friedman v. Jablonski, 371 Mass. 482, 358 N.E.2d 994, 997 (Mass. 1976), and its ilk adds nothing. Defs. Br. at 38-39. In Friedman, the court found that at the time of sale a purchaser of real estate was charged with knowledge about a right of way allegedly running with the land because "[a] right of way is an interest in land which might appear of record in the registry of deeds." 358 N.E.2d at 997. Here, unlike *Friedman*, there were no public, legal documents (like a deed) that Plaintiffs could access, and search, to uncover the true sale price from year to year for each Subject Drug. Defendants' other cases are distinguishable on the same grounds. See Wise v. Hubbard, 769 F.2d 1 (1st Cir. 1985) (patent was on file and available for public inspection at U.S. Patent Office and over 400 public and university libraries across the country); Duco Assocs., Inc. v. Lipson, 11 Mass. App. Ct. 935, 416 N.E.2d 555 (Mass. App. Ct. 1981) (misrepresentation of rental income was not inherently unknowable because the rents were on file with the local rent control board); Frank Cooke, Inc. v. Hurwitz, 10 Mass. App. Ct. 99, 406 N.E.2d 678 (Mass. App. Ct. 1980) (plaintiff and its law firm had ready access to paperwork and public records demonstrating that loans were unsecured).

C. Plaintiffs Can Demonstrate Fraudulent Concealment

The federal doctrine of fraudulent concealment operates to toll the statute of limitations "where a plaintiff has been injured by fraud and remains in ignorance of it without any fault or want of diligence or care on his part." *In re Lupron*, 295 F. Supp. 2d at 183 (citations omitted).

To invoke the doctrine of fraudulent concealment, a plaintiff must plead and prove three elements: "(1) wrongful concealment of their actions by the defendants; (2) failure of the plaintiff to discover the operative facts that are the basis of his cause of action within the limitations period; and (3) plaintiff's due diligence until discovery of the facts." *Id.* (citing *Berkson v. Del Monte Corp.*, 743 F.2d 53, 55 (1st Cir. 1984)).²

Defendants claim that no material issue of fact stands in the way of summary judgment in their favor on the issue of fraudulent concealment (Defs. Br. at 39-40), but there is substantial if not compelling evidence that Defendants concealed the true prices of the Subject Drugs. First, Defendants' contracts contained confidentiality clauses, which prohibited the buyers (including doctors and PBMs) from revealing the prices they were paying to anyone, including payors. *See* Ex. 15 (1992 OBI contract with Caremark, ¶ 7); Ex. 16 (1993 OBI contract with Stadtlanders); Ex. 17 (AZ form Urology contract, ¶ 6 (requiring terms and existence of contract remain confidential); Ex. 18 (1995 SPW contract with Massachusetts physician group requiring confidentiality of all pricing during term of contract and three years afterward).

Second, Defendants routinely provided discounts to providers below WAC, which is the lowest publicly available pricing benchmark. These price reductions were in the form of "off invoice discounts," rebates or administrative fees. *See*, *e.g.*, Exs. 15 and 16 (OBI 1992 and 1993 contracts providing performance allowances, discounts and rebates); Ex. 17 (AZ urology contract offering discount of 32-50% off WAC); Ex. 18 (1995 SPW contract with Massachusetts physician group providing confidential pricing terms of greater than 95% off of AWP for albuterol products); and Exs. 19 and 20 (SPW internal corporate documents revealing SPW's

² The doctrine of equitable tolling is also available to Plaintiffs to toll the statute of limitations because, for the same reasons, Plaintiffs satisfy the elements for fraudulent concealment, and the evidence supports finding that Plaintiffs were actively misled by Defendants. *See Jensen v. Frank*, 912 F.2d 517, 521 (1st Cir. 1990).

participation in a special, verbal arrangement with Rite-Aid that began in 1995 offering prices for Warrick labeled drugs that represented discounts between 70-80% off AWP). Indeed, BMS managers testified that the discounts that BMS offered its customers were confidential. BMS's former Director of Marketing for Oncology, Christof Marre, testified to the various ways in which BMS provided discounts off of WLP: contract pricing; rebates; admin fees; and marketing fees. Ex. 21 (Marre Dep. at 78-79). If provided, all forms of discounts would always appear in a contract, were not made public by BMS or any publication, and would not be reflected in the WLP. *Id.* (Marre Dep. at 82-84). Marre confirmed that contract pricing is always less than WLP, and that contract prices are confidential and not publicly available. *Id.* (Marre Dep. 37-38); *see also* Answer ¶ 192 (BMS admits "that certain price discounts it gives to customers are confidential competitive information ") (Dkt. No. 800).

Third, Defendants' own secretive behavior reveals the active concealment of their schemes and their recognition that such schemes were wrong. Examples abound. In the mid-1990s, the manufacturers – allied with ASCO – actively discouraged governmental surveys of actual prices in the marketplace. For instance, Dolly Hanrahan, Defendant Abbott's Washington lobbyist, in discussing HCFA's efforts to conduct EAC surveys reported that "ASCO is working directly with [OMB] to essentially kill the survey based on grounds that HCFA has not followed administrative procedures." Ex. 22 (TAPGB08146). Acknowledging HCFA's lack of "manpower to meet all the requirements of the OMB to statistically validate the drug survey process," a TAP lobbyist approvingly referred to the state of affairs as "a 'Bureaucratic Mexican Standoff." Ex. 23 (DD0082). Manufacturers could have stepped up and assisted the market by disclosing true prices, but Ms. Hanrahan reported that ASCO preferred that the drug manufacturers not address the survey issue, and that "[1]egal counsel for Bristol-Myers concurs

saying that it would only agitate the situation further, particularly since HCFA is focused on high volume drugs." *Id.*; Ex. 22 (TAPGB08146).

In referring to the cancellation of the HCFA survey as "fortunate for us," J&J acknowledged that "[i]f [HCFA] had done a survey and come up with an average price, this would have changed reimbursement [for Procrit]. . . . *Right now they do not know what the cost is for different providers*." Ex. 24 at 58842 (emphasis added); *see also* Ex. 25 (Dooley Dep. at 536).

Defendants regularly cautioned physicians and their own sales representatives not to reveal actual transaction prices to insurers: "if we were to routinely use cost to wholesalers we would set payers' expectations too low." Ex. 26 (memo from Centocor's Michael Ziskind, cautioning sales representatives to use different "costs" for different audiences). Clearly, as late as 1999, Centocor believed that payers did not comprehend the spread between real prices and AWP, and did not want such payers to learn the truth.

When Defendants did communicate with the federal government, they went out of their way to avoid revealing the true prices they were charging. A glaring example is Defendant J&J's Procrit, where "the Dooley emails" evidence the fact that in August 1996 and January 1998, J&J certainly did not think the government and private payors were aware of the actual spreads on Procrit. *See* Ex. 27 and 24. Defendants' belief that the spreads were hidden is itself enough to deny summary judgment on the basis of the statue of limitations. Similarly, when asked by the federal government what the wholesale price of Remicade was, Defendant J&J's Centocor did not reveal its true price to wholesalers, but instead reported the AWP as the wholesale price. *See* Ex. 28 (Remicade J-Code Application). And as early as 1995, AZ was

concerned that "HCFA may see through" AZ's discounting and spread marketing strategy and "take offense." *See* Ex. 29 (Patterson Pricing Memorandum, AZ0237164-169, at 167).

In one instance in 1996, AstraZeneca developed a complicated way to increase the spread on Zolodex but to avoid any "regulatory/legal/public relations risk" and make AZ appear to be "responsible" or "patient friendly" by setting the AWP just below the competing drug while still offering bigger discounts on the actual purchase price. *See* Ex. 30 (AZ0024479-81). This is direct evidence of AZ's intent to fraudulently conceal the true pricing of Zolodex. Similarly, the main reason Schering created Warrick was to use that company as a shell corporation to hide the true prices being charged for Schering-Plough products. *See* Plaintiffs' Memorandum in Opposition to Schering-Plough Corporation's and Warrick Pharmaceuticals Corporation's Motion For Summary Judgment as to Class 2 Claims at Section II.A.

For its part, BMS took other actions to conceal its unlawful practices. Greg Bell, BMS's consultant who, incredibly, is proffered by BMS here as an "independent expert" witness, as part of a lucrative consulting contract advised BMS to discuss "[e]conomic issues" in a "low key manner" with customers and use "[n]o printed materials." Ex. 31 (BMS/AWP/01233108-184 at 01233134).

Although GSK has settled out, its actions are relevant to this issue because it reflects industry-wide behavior. Like other Defendants, GSK took actions to conceal its AWP manipulation. In March 1996, SKB sought advice from its reimbursement consultant, Health IQ, on how to counter "Glaxo's latest attempt to 'gouge' the Medicare system." Previously, Health IQ, using an alias, had written to Medicare Part B payment intermediaries on behalf of SKB to highlight Glaxo's improper pricing practices. But this time Health IQ cautioned Glaxo not to draw HCFA's attention to spreads:

Health IQ is concerned that highlighting the difference between the actual acquisition cost and the published AWP may not only increase attention to Glaxo's pricing practices, but may provide the impetus for HCFA to implement a system that could impact not only reimbursement of anti-emetics, but all pharmaceutical and biological products. The ramifications could extend well past Medicare to include Medicaid programs (also administered by HCFA) as well as private payors (who tend to mimic policies and procedures implemented by public payors). Therefore, Health IQ feels it would be best not to pursue this matter with the Medicare Part B Medical Directors.

Ex. 32 (Mar. 15, 1996 letter Health IQ to Bob Boate (P007133-34)).

Defendants also sought to time price increases in a manner that would not draw governmental attention. For example, in March 2000 an SKB manager, responding to a request for a price increase recommendation, advised that "[d]ue to greater government focus on injectable drug pricing in the oncology clinic setting, it is wise for SB to further space the timing between price increases on Kytril." Ex. 33 (Memorandum from Pearl Pugh to Kevin Lokay, GSKMDLLKYTR02-0043706-07). J&J's OBI subsidiary has also made persistent efforts to ensure that its pricing changes did not trigger a governmental pricing survey. For instance, when OBI considered taking a price change, it was careful not to raise its list price above that of Epogen because OBI did not want to provoke attention from HCFA, which could lead to "acquisition, FSS or ESRD reimbursement rate[s]" in the non-dialysis setting. Ex. 34 (at 61052); Ex. 35 (Webb Dep. at 103).

As noted by the federal government in its Sentencing Memorandum filed in the case *United States v. TAP Pharm. Prods., Inc.*, No. 01-CR-10354-WGY (D. Mass.), AstraZeneca concealed both its fraudulent marketing and that of its competitor, TAP:

[I]n 1995, TAP, in a moment of delicious irony, accused its competitor, [AstraZeneca], the manufacturer of Zoladex, with providing inducements to physicians in violation of the Medicare

fraud and abuse laws, to include the fact that employees of the competitor were giving free samples to doctors to encourage them to switch from Lupron to Zoladex. [AstraZeneca], in turn, accused TAP of the very same conduct. Top employees from the two companies met in a summit meeting to discuss this exchange of criminal allegations. Did the serious allegations curb TAP's conduct? Did TAP, aware of allegations that its employees had engaged in criminal conduct, undertake expeditiously to stop the behavior, to train its employees in the rules and to enforce their adherence to the rules? Did either company, in possession of information that a competitor was violating the rules, report the conduct to prosecutive authorities in an effort to clean up the industry? Unfortunately, the answer to all of these questions is no: TAP, cognizant of the rules and having been accused of violations, simply carried on its business as it always had, full criminal speed ahead.

See Ex. 36 (Sentencing Memorandum of the United States, at 62-63). As TAP advised doctors:

Doctor, by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCFA then realizes that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amount you may charge.

Ex. 37.

Not only did Defendants conceal the true nature of their wrongdoing from outsiders, they also actively lobbied to preserve the very system that they were exploiting. For instance, BMS lobbied the federal government to maintain AWP-based reimbursement for Part B drugs:

Continued Medicare Part B Battle. This past year, we worked closely with Oncology on the Medicare Part B Reimbursement Issue with a very favorable outcome (instead of Oncology drug reimbursement being based on actual acquisition cost, which was proposed by the Administration, reimbursement will be based on 95% of the AWP. While this was a major success, the 95% number could be easily lowered in subsequent sessions of Congress. . . . We need to actively manage this issue.

Ex. 38 (Dec. 5, 1997 Memorandum from Ron Miller to Mark Durand re: Oncology Policy Issues, BMS/AWP/000153461); *see also* Ex. 39 (evidencing Zeneca's lobbying of Medical Directors to maintain Zoladex reimbursement at AWP and to not survey for actual prices).

If "everybody knew" or should have known about Defendants' unfair and deceptive acts and practices, and the full nature and scope of those acts and practices, Defendants would not have taken affirmative steps to conceal their control and inflation of AWP and their promotion of spreads. As Judge Stearns' observed about the AWP inflation in the *Lupron* case, "[i]f everything [about Lupron®] was known to everybody, why did [d]efendants emphasize secrecy?" *In re Lupron*, 295 F. Supp. 2d at 168 n.19. The answer is manifest: Defendants took these actions because they knew that payors were not aware of Defendants' fraud. There is ample evidence that Defendants worked to affirmatively conceal their true prices from the government, insurers and the Class. This evidence supports the point detailed above that any investigation of prices undertaken by members of Class 3 would not have revealed the true prices of the Subject Drugs or the existence of the massive fraud alleged here. At a minimum, there is genuine issue of material fact on this issue, denying summary judgment in favor of Defendants.

V. DEFENDANTS' FAILURE TO MITIGATE CHALLENGE FAILS

Just like the statute of limitations claims, a claim of failure to mitigate damages is a factual determination that is not appropriate for summary judgment. *Commonwealth v. TLT Constr. Corp.*, 1999 Mass. Super. Lexis 252, at *6 (Mass. Super. Ct. 1999). Defendants' own citations fully support this notion, as each case relied on by Defendants dealt with mitigation during or after trial and not at the summary judgment stage of the proceedings. *See Knapp Shoes, Inc. v. Sylvania Shoe Mfg. Corp.*, 72 F.3d 190, 204-05 (1st Cir. 1995) (mitigation issued raised during bench trial); *DiVenuti v. Reardon*, 37 Mass. App. Ct. 73, 637 N.E.2d 234, 236

(appeal following trial); Savers Prop. & Cas. Ins. Co. v. Admiral Ins. Agency, Inc., 61 Mass.

App. Ct. 158, 807 N.E.2d 842, 849-50 (2004) (appeal following jury trial); Cambridge Plating

Co., Inc. v. NAPCO, Inc., 85 F.3d 752 (1st Cir. 1996) (appeal following trial).

In any event, a plaintiff is not under any duty to take outlandish chances in order to mitigate its damages; nor is the plaintiff "obligated to play the seer, choosing the course of action that would, in hindsight, have turned out best." *Veranda Beach Club Ltd. P'ship. v. Western Sur. Co.*, 936 F.2d 1364, 1386 (1st Cir. 1991). Defendants bear the burden of proving by fair preponderance that the injured party failed to take *reasonable* steps to hold down its losses. *Id.* Defendants have clearly not met this burden, and therefore, their motion for summary judgment must be denied.

Defendants' suggestion that Plaintiffs should have implemented an immediate change to the entire pharmaceutical reimbursement system only underscores the insidiousness of their fraud. Defendants are (and were) fully aware that without a critical mass of participants, and huge capital expenditures, it would be impossible for any single Plaintiff or Class member to effect any changes on the industry as a whole in order to counteract the AWP scheme. *See, e.g.*, Ex. 2 (Mulrey Dep. at 65, 72); Devaux Decl., ¶ 12; Hartman Class 3 Decl., ¶¶ 14, 25(c). Defendants thus overlook critical market structural impediments to reforming the system *even if Class 3 had learned the full extent of Defendants' fraud*. As Dr. Hartman has outlined, it is difficult and expensive for payors, even large payors, to track all pricing information for all drugs.⁵⁷ Consequently, commonly understood notions of bounded rationality and administrative

⁵⁷ "Even when payors attempt to track information on drugs and the acquisition costs of drugs; even when the right to audit a PBM exists; and even when prescription drug benefit consultants are retained, there remains considerable non-transparency in the contracts, . . . billing information and accounting information. This fact is made vivid by the continued and recent attempts by payors to obtain greater pricing transparency from middlepersons and providers." Dec. 16, 2004 Hartman Class Cert. Decl., ¶ 57(b) (footnotes omitted).

efficiency command that payors utilize common "rules of thumb" such as the AWP metric in order to adjudicate claims. Dec. 16, 2004 Hartman Class Cert. Decl., ¶ 57(a). As Dr. Anderson, Professor of Medicine and Health Policy at Johns Hopkins, testified in *Lupron*, with 65,000 drugs "negotiation of a specific price for each . . . would be administratively impossible," thus fostering the AWP pricing standard. Hartman S.J. Opp. at 67 n.96. Even BMS recognized that AWP was "the only easily obtained published price source." Ex. 14. An industry cannot just simply abandon a market-wide pricing metric at the drop of a hat, even if individual participants wanted to. Its participants need time to absorb learning, rewrite systems, and get extensive provider networks on board. Moreover, "before a major shift occurs in operational practices, the institution wants to observe whether the newly acquired information is indicative of a real change in the economic terrain in which that institution competes." Hartman Class 3 Decl., ¶ 15(b). Thus, even if market participants had extensive knowledge of Defendants' schemes – and they did not – the very nature of the AWP system would prevent them from taking dramatic action to quickly change business practices.

Defendants knew that any payor who attempted a variation risked both confusion and backlash from the providers who utilized the standardized system. Of course, the obvious resolution was for Defendants to simply stop their unlawful inflation of what should have been the "average wholesale price" for each product. Defendants chose not to and cannot be heard to complain that Plaintiffs failed to mitigate.

Defendants' reliance on *Cambridge Plating Co., Inc. v. NAPCO, Inc.*, 85 F.3d 752 (1st Cir. 1996), only highlights Plaintiffs' argument. As Defendants' brief points out, the missing system component at issue in *Cambridge Plating* took only one day to install and yielded immediate system performance. Defs. Br. at 42. Here, implementing any change to the

reimbursement system would be a massive undertaking and would require uniform acceptance on a national level. Terminating the use of AWP certainly does not equate to the installation of one missing component. Defendants offer no evidence to meet their burden of proof that class members could have abandoned the AWP system in a quick, *reasonable*, and cost effective manner.

VI. CONCLUSION

For the foregoing reasons, summary judgment in favor of the Track 1 Defendants on these Class 3 issues should be denied.

DATED: August 30, 2006. By /s/ Steve W. Berman

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on August 30, 2006, I caused copies of **PLAINTIFFS' OPPOSITION TO THE TRACK 1 DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH RESPECT TO CLASS**3 to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
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